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GUIDING VALUES: ARGENTINE STEM CELL RESEARCH AND REGENERATIVE MEDICINE

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Policy Brief 4:2010

Drawing on empirical research conducted in Argentina through the ESRC-funded 'GET: Social Values Project' (see <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>), this Policy Brief (1) highlights the importance of moral foundations to science and regulation, (2) provides evidence of Argentine stakeholder views on the appropriate source of moral values for science boundary-setting, (3) provides evidence of Argentine stakeholder views on the values most important to the governance of stem cell and regenerative medicine research, and (4) offers recommendations on how to incorporate this evidence into bioscience and health research policy options in Argentina.

THE IMPORTANCE OF MORALITY

It has long been the view that science is not value-free and that activities in the biomedical research setting ought to be solidly grounded on the essential values of mankind.¹ Similarly, it is generally recognized that law (and regulation) must have some moral basis if it is to be persuasive and legitimate, particularly where the subject conduct has some potential to harm.² Ultimately, moral values are important to the realization of both good science and good governance, particularly where human health and wellbeing is implicated, and there is ample justification for their formulation in 'biolaw', which, by necessity, concerns matters having a strong a moral element.³ However, values are often more assumed than explicit, and are often extremely opaque or hidden, and therefore invisible. One objective of the GET: Social Values Project was to make visible and explicit some of the values that Argentine stakeholders feel should influence the biomedical research setting and the legal and regulatory solutions created to solve actor problems in this arena.⁴ Exposing such values can enhance position comprehension and mutual understanding, and therefore discussion around ideals and trajectories for science and its regulation. It can lead to deeper understandings, and, when approached positively, increase the potential for consensus.

SOURCES OF MORAL VALUES

Respondents in the GET: Social Values Project were asked to identify important and/or valued sources or shapers/informers of moral values.⁵ Collectively, they felt that core moral values should be derived from conversations around the following sources: (which are not here ranked or listed hierarchically):⁶

- the Hippocratic Oath;
- moral theory based on rationality and common sense;

"[Moral values should come] from ethics theory, not from religion. And not from ambiguous slogans, like 'human dignity' or 'sanctity' dogma."

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1. See E. McMullen, "Values in Science" in PSA, Proceedings of the Biennial Meeting of the Philosophy of Science Association, vol. 2 (USA: U of Chicago Press, 1982) 3-28, regarding the former, and F. Mayor, "Preface" in *Proceedings of the First Session of the IBC* (Paris: UNESCO, 1994), regarding the latter claim.

- academic scholarship concerning justice and risk;
- international human rights ideas;
- spiritual writings (but not religious dogma).

Such a ‘conversation’ was viewed as absolutely essential insofar as it would encourage a range of stakeholders to consider the consequences of actions, and therefore a range of options, before acting.

Clearly, the idea of discussion and debate was felt to be important to uncovering, exploring and refining values. Respondents specifically noted the social and dynamic nature of morality for which there could be no universal rule, and they felt that values must come from society; from informed people who are prepared to debate and to openly articulate moral values and defend the research boundaries they inform. In short, social sources need to be consulted so as to generate good evidence and understanding. Respondent 18 considered humans to be connected in a broad and loose way, so both individual judgments and communities are important in serving as a source of values. Complementing this, several respondents cited the importance of education to the development of values and morality; education and the encouragement (and training) of rationality were viewed as important sources, and lack of education was seen as a danger to moral thinking.

Despite a high level of agreement about the shared, social and evolutionary nature of values (and the morality which those values inform), respondents all acknowledged the importance of individual judgments. Many respondents readily expressed scepticism toward religious institutions as a source, together with a strong doubt that such institutions could have any positive impact on the exercise of exploring moral values (or the development of rational biomedical research regulation). Rather, they felt that moral values must come from outside the two (perceived) antagonists (ie: outside religious and science circles).

MORAL VALUES FOR THE BIOSCIENCE SETTING

Respondents in the GET: Social Values Project articulated a broad range values which they considered to be important not only to the bioscience and regulatory setting, but to Argentine society more generally. The values which they felt were broadly important (for Argentina and beyond) were as follows:

² See H. Hart, *Law, Liberty and Morality* (Stanford: Stanford U Press, 1963), P. Devlin, *The Enforcement of Morals* (NY: OUP, 1968), R. Dworkin, *Life's Dominion* (London: HarperCollins, 1993), and others.

³ So argued in S. Harmon, “Control of Reproductive Treatment and Research: From the Moral to the Political to the Legal – and Back Again?” in C. Lyall, J. Smith & T. Papaioannou (eds.), *The Limits of Governance: The Challenge of Policy-Making for the Life Sciences* (Aldershot: Ashgate, 2009) 79-104.

⁴ For purposes of the GET: Social Values Project and this Policy Brief, the concept of ‘values’ is interpreted as being deeply held ideas, beliefs or moral concepts which contribute to personal and social identity. They are broader and more cross-contextually relevant (ie: more diffuse) than ‘principles’, which are viewed as lower level concepts more practically grounded, and more mechanistically directed.

⁵ There were 22 respondents who participated in the GET: Social Values Project. They were drawn from executive, legislative and regulatory bodies, the clinical and medical research communities, and the legal and ethical academic communities.

⁶ The identification of these sources expose a blend of consequentialist and deontological approaches. In the interviews, considered holistically, respondents were very concerned with consequences, although this did not always lead them to adopt strictly consequentialist approaches. Deontologically-sounding rules were also referenced or identified as being useful.

"I respect religion. I am Catholic. But I separate completely. And if there is a problem, I look from this, from this, from this [angle]. Factual."

"The protection of human dignity. And please notice that I don't say human lives, I say human dignity, because not always are [they] the same. But I would say that we have to speak a lot about human dignity. People think it is very simple, but it is not. It is a very difficult subject."

- **Dignity:** This is a broad value which seeps into all others in some way. It was felt that we must recover the notion of the importance of humanity and of respecting people and frailties and vulnerabilities and potentialities. It requires a balancing of research with other values, always being careful not to instrumentalise people.
- **Human Wellbeing:** Everything depends on human health. It is important to protect life, health, and wellbeing. The restrictions placed on the pursuit of improving human wellbeing should be minimal. Wellbeing, as a value, was tied to the conception of public or population health, which relies on a greater connection being made between research and clinical use (ie: research actions must have some public or population utility). One respondent argued that Argentina cannot compete economically so it needs to use funds in wise ways to develop experience and translate research into clinical uses.
- **Solidarity:** This value focuses on social contacts, interconnectedness, emotional ties to others, and the common good. It reminds us of our obligations to take care of people and help those in a weaker position to have some possibilities and to live with freedom. It makes 'public ethics' important, which means we should measure the value of actions by how well they avoid selfish ends and generate social benefit (ie: are directed at solving society's problems).
- **Justice:** This value embodies equality and equity. It demands the protection of the rights and wellbeing of everyone, especially the weak or vulnerable, and the just sharing of benefits throughout society (ie: the benefits of research must be made available and optimised).
- **Democracy:** This is an encompassing value that implicates engagement, participation, contribution, and societal control. As a moral concept, it encourages participation in boundary-setting and trajectory-determining (ie: good science needs more than invested scientists thinking about it). It also embodies open debate and idea-exchange. Governance efforts must recognise that no one has the absolute truth, but it must at the same time provide limits. Democracy also acknowledges plurality, which is a reality in Argentine society. There must therefore be a minimum level of liberty to act independently so long as others are not injured. Finally, democracy encourages accessibility of the governance framework (ie: the regulatory environment should not be too complex or rigid).
- **Knowledge:** Knowledge is a value in itself, and needs to be generated within moral bounds, but in doing so, it is appropriate to push boundaries. As part of this, creativity is very important; innovation in ways of thinking and opening up new pathways for creative thought.
- **Autonomy:** This is based on free will, self-rule, and the creation of space for people to make decisions about themselves and for themselves. People must be allowed to act in accordance with their feelings and desires. Thus, donors, subjects and patient must receive adequate *information* so they can weigh options and make an informed decision (to *consent* to certain courses or refuse certain courses), and it imposes on

"I have very simple ways of defining morality. For me, it would be sentences like, 'Don't do to the others the things that you don't want to be done upon you,' and 'Defend the rights of the people in terms of equality and justice.'"

"I love what you call the value of solidarity, I think it is important because it includes the importance of more emotional attachment to others. And I am absolutely convinced that that is an essential part of a moral being, to be emotionally attached to others, to be close to others in the community."

others the responsibility to hold personal information in confidence and to protect the *privacy* of others. It also grounded the idea that people should retain control of their body and their body parts and products.

Respondents in the GET: Social Values Project also had strong (and largely overlapping and consistent) views about the values that must shape the medical research undertaking itself, including researcher and physician action. Key values repeatedly identified were:

- **Honesty:** Researchers and physicians must be honest with patients, about patients, with research data, and they must not promise to do one thing and then do another. Researchers must avoid hyperbole and inflated claims.
- **Safety:** Donors, subjects and patients must be protected from harmful actions. They must not be put at undue risk, and they must not be sold treatments that are not proved (eg: protect patients and research subjects). This value is closely allied to non-maleficence (do no harm) and beneficence (actively do good), and it encourages us to avoid unnecessary risks, manage acceptable risks, and improve the quality of life of people, and to do so by understanding that only 'good science' must be pursued.
- **Scientific Freedom:** This is the idea that a society must recognise some minimum level of liberty to act (and conduct research) in accordance with your own feelings and values so long as others are not injured. This is important in a plural society. Researchers have a responsibility take opportunities and push boundaries, but in the understanding that they have responsibilities to society; they must rely on, and generate, good evidence (eg: scientific veracity), and they must abide by research and clinical standards.
- **Transparency/Trust:** This value imposes on researchers the need to be open about what they are doing and what they hope to achieve. Publics have the right to know the scope and purpose of research, research risks, benefits and expectations, researcher conflicts, and what is behind the research (ie: the source and provenance of tissue sources). Research must be transparent, its governance must be transparent, researchers should be called upon to defend and/or explain their work, and they should be expected to record and make public their work. All of this will promote public trust.

CONCLUSIONS AND OBSERVATIONS

Despite the (perhaps surprising) number and range of values exposed, there is very little that appears to be particularly 'Argentinean' or distinctive about these values. In many ways, they reflect (and perhaps add to) the values claimed by emerging international biolaw to be 'universal'. This may be unsurprising given that (1) many of the respondents received at least some of their education abroad (particularly in the USA), (2) some of the respondents rely on (or frequently have reference to) foreign or international professional standards, and (3) some of the respondents are involved in international collaborations (often with American and European partners). What may emerge as particularly 'Argentinean' is the way that these values are marshalled or deployed, and to what end. This is obviously an area worthy of further study, and, in fact, is the basis of further

"[T]he only way to find [cures] is to research, and that is very important and necessary. [T]he main value is health and to find solutions for many things."

"[It] is very important to open the debate and to have opposite visions of the subject sitting at the same table and think that maybe both have rights; that not one has the truth and one has not - maybe both have the truth. You need to really conclude what is the best for the country and for the people of the country."

"I love discussion and want to open up the ideas of the people."

projects being developed by the PI, Co-I and other partners.

The above value evidence does not support any specific recommendations on how to proceed in Argentina from a governance or a regulatory point of view. However, this evidence does support some important observations:

- **No General Rule:** A general rule, particularly a general prohibition in science, even one morally grounded, was considered by most respondents to be inappropriate because in every situation you must have the ability to rank values (ie: absolutes are unhelpful).⁷ Policymakers should avoid imposing blanket prohibitions to scientific pursuits.
- **Ranking Values:** Respondents considered the ranking of the above values to be a social enterprise which requires debate. Such a debate (about values and bioscience) has not yet happened in Argentina. Policymakers and practitioners should take steps to begin engaging with different publics on the issue of values considered important to Argentina and to scientific advancement in Argentina, and should probe publics about desired health, healthcare and health research futures.
- **Boundary-Setting:** Respondents felt that limited and rational boundaries for scientific research were appropriate and could encourage both good science and public trust and support. Policymakers and publics should collaborate to set boundaries for science research, focusing on the professional responsibilities in the field, and ensuring that limits set are rationally defensible with reference to these values.

"Autonomy, free will and options. But again, I think that the primary concern should be considering [these] in light of the vulnerability of our citizens."

"If God made us, He gave us intelligence to research medicine and to improve our situation, and therefore it is important for researchers to have freedom to develop science."

⁷ One respondent argued that ethics considered in a vacuum is unhelpful. There must be a context – a problem – within which one must bring these values to bear.



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